

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/
FENFLURAMINE/DEXFENFLURAMINE)
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

v.

CIVIL ACTION NO. 99-20593

AMERICAN HOME PRODUCTS
CORPORATION

2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8435

Bartle, C.J.

March 18, 2010

Kathleen Truehart ("Ms. Truehart" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Ververlena M. Truehart, Ms. Truehart's mother, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Joseph S. Weinstein, M.D., F.A.C.C. Based on an echocardiogram dated April 16, 2003, Dr. Weinstein attested in Part II of Ms. Truehart's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on such

3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Weinstein also attested that claimant suffered from mild
(continued...)

findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$512,025."

In the report of claimant's echocardiogram, the reviewing cardiologist, Michael A. Rubin, M.D., stated that claimant had "[m]oderate [mitral regurgitation] with regurgitant jet fraction [of] 26%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In May, 2005, the Trust forwarded the claim for review by Nancy V. Strahan, M.D., one of its auditing cardiologists. In audit, Dr. Strahan concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. In support of this conclusion,

4. (...continued)
aortic regurgitation. As Ms. Truehart's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

Dr. Strahan explained that claimant had "no [mitral regurgitation] only backflow."⁶

Based on the auditing cardiologist's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Ms. Truehart's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant submitted a supplemental report from Dr. Weinstein, who confirmed his previous finding of moderate mitral regurgitation. In particular, Dr. Weinstein stated that "[t]he mitral regurgitant jet fraction was documented at 26%. This echocardiogram was read by a board certified cardiologist who has read thousands of echocardiograms. Upon review, we feel that the results are as originally documented." Claimant also argued that the Trust referred her to Dr. Weinstein because he participated in the Trust's Screening Program, and, therefore, she assumed that "he would have filed an accurate diagnosis."

6. Although Dr. Strahan stated that the quality of claimant's echocardiogram tape was "very poor," she noted in her report that the tape was evaluable.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Truehart's claim.

See Settlement Agreement § IV.A.1 (Fund A screening program established under the Settlement Agreement).⁸

The Trust then issued a final post-audit determination, again denying Ms. Truehart's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Truehart's claim should be paid. On February 13, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5986 (Feb. 13, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant did not file a response to the Trust's statement of the case, thereby relying only on the materials submitted during the contest phase. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and claimant have had

8. In addition, claimant argued that the purported poor quality of her echocardiogram tape should invalidate Dr. Strahan's audit findings. As discussed above, however, Dr. Strahan noted in her report that claimant's echocardiogram tape, although of poor quality, was evaluable.

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are
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an opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of

9. (...continued)
conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

moderate mitral regurgitation.¹⁰ Specifically, Dr. Vigilante concluded that:

The mitral regurgitation jet was most impressive in the apical four chamber view. The mitral regurgitation was only mild in this view. The representative images of the mitral regurgitation jet and left atrium were digitized and measured off-line. The RJA/LAA ratio was less than 15% in the most impressive cardiac cycle for mitral regurgitation. Most of the cardiac cycles demonstrated RJA/LAA ratios of less than 10%. The mitral regurgitation was also mild when evaluated in the apical two chamber view. The RJA/LAA ratio was less than 10% in the cardiac cycles which evaluated mitral regurgitation in the apical two chamber view. The supposed RJA planimetered by the sonographer on the echocardiogram tape was inaccurate. Low velocity non-mitral regurgitant jet flow was included within this inaccurate measurement. The accurate RJA/LAA ratio was always less than 15% in this study.

In response to the Technical Advisor Report, claimant submitted a chart summarizing the findings of each physician who reviewed her echocardiogram tape. Claimant requested that the court adopt Dr. Weinstein's and Dr. Rubin's findings of moderate mitral regurgitation.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not contest the specific analysis provided by either Dr. Strahan or Dr. Vigilante. Claimant does not address Dr. Strahan's finding that claimant had "no [mitral regurgitation] only backflow." Nor does claimant refute

10. Dr. Vigilante also noted that "[a]lthough this was a below average study, this echocardiogram was definitely interpretable."

Dr. Vigilante's conclusion that claimant's "RJA/LAA ratio was less than 15% in the most impressive cardiac cycle for mitral regurgitation" and that "[t]he supposed RJA planimetered by the sonographer on the echocardiogram tape was inaccurate." On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Moreover, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include:

- (1) failing to review multiple loops and still frames;
- (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram;
- (3) failing to examine the regurgitant jet throughout a portion of systole;
- (4) over-manipulating echocardiogram settings;
- (5) setting a low Nyquist limit;
- (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation;
- (7) failing to take a claimant's medical history; and
- (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Strahan and Dr. Vigilante determined, and claimant does not dispute, that her attesting physician relied upon inaccurate measurements. Specifically, Dr. Strahan noted that the measurements included "backflow," and Dr. Vigilante concluded that the measurements included "[l]ow velocity non-mitral regurgitant jet flow." Such unacceptable practices by claimant's attesting physician and expert cannot provide a reasonable

medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because the echocardiogram that forms the basis of her claim was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. Claimant's reliance on the echocardiogram obtained as a result of the Screening Program is misplaced. The Settlement Agreement clearly provides that the sole benefit that a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Settlement Agreement, § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to

seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662 (Nov. 26, 2002), which mandated a 100% audit requirement for all claims for Matrix Benefits. See, e.g., PTO No. 2662 at 13. As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Truehart's claim for Matrix Benefits and the related derivative claim submitted by her mother.